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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/396,446	02/28/95	AHLIWAIA	G 00216/289001

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15M2/0708

HARRIS EXAMINER	
ART UNIT	PAPER NUMBER
1501	4

DATE MAILED:

07/08/96

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

Office Action Summary

Application No.
08/396,446

Applicant(s)
Ahluwalia et al.

Examiner
Robert H. Harrison

Group Art Unit
1501



☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-74 is/are pending in the application.

Of the above, claim(s) 2-7, 9-20, 30-41, and 44-74 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1, 8, 21-29, 42, and 43 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Receipt is hereby acknowledged of applicant's preliminary amendment filed as of April 23, 1995; prior art filed as of June 15, 1995 and communication filed as of January 22, 1996.

Claims 1-74 are generic to a plurality of disclosed patentably distinct species comprising one patentably distinct species (or independent invention) per MPEP § 803, 809.02(d) (Markush group claim practice, separate and burdensome fields of search required), select one from each of: the encompassed ultimate species of the nonsteroidal suppressor of angiogenesis selected from one of those set forth in the instant specification. Each nonsteroidal suppressor of angiogenesis requires a separate and burdensome search in one or more of the subclasses of Class 514, there being no home or subclass for the enumerable nonsteroidal suppressor of angiogenesis as set forth in the instant claims.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or

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admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

Applicant is further required to identify the claims that correspond to the election as well as those that do not, even if the requirement is traversed.

During a telephone conversation with Robert C. Nabinger on March 21, 1996 a provisional election was made with traverse to prosecute the invention of mycophenolic acid as the nonsteroidal suppressor of angiogenesis, claims 1, 8, 21-29, 42 and 43. Affirmation of this election must be made by applicant in responding to this Office action. Claims 2-7, 9-20, 30-41 and 44-74 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

Claims 1, 8, 21-29, 42 and 43 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "inhibiting" in the claims is a relative term which renders the claims indefinite. The term "inhibiting" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree or degree of inhibition and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. See Amgen v. Chugai.

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. 112, first paragraph, as failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

As the cited reference provided with this Office action discloses mycophenolic acid contrary to being a hair growth inhibitor is a hair growth stimulating compound and thus one of ordinary skill in the art could not practice the invention as claimed. The Examiner notes applicant's specification appears to be a shotgun specification for a whole slew of compounds and mycophenolic acid has not been disclosed or specifically singled out for inhibition of hair growth but appears to be only a "paper example" of an active which is contemplated or will be obtained at some future date experimental data showing mycophenolic acid as useful in inhibiting hair growth. However, prophetic test systems are not considered to provide any basis for presuming that the claimed method of treating using mycophenolic acid is enabled in mammalian subjects or human hosts. It is well known and established that "law requires that disclosure in an application shall inform those skilled in the art how to use

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applicant's alleged discovery, not ^{how} to find out to use it for themselves." In re Gardner et al., 166 USPQ 138 (CCPA 1970).

Claims 1, 8, 21-29, 42 and 43 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Future Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert H. Harrison, whose telephone number is (703) 308-2422. The examiner can normally be reached on Monday-Friday from 9:30 A.M. to 6:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John C. Bleutge, can be reached on (703) 308-2363. The fax telephone number for this Group Art Unit is (703) 305-5246.

Any inquiry of general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-2351.

RH
RHHarrison:cdc

June 26, 1996



MELVYN I. MARQUIS
PRIMARY EXAMINER
GROUP 1501